Microincision cataract surgery with implantation of a bitoric IOL using an enhanced program for IOL power calcuation

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Abstract:.

Purpose: To evaluate the potential benefit of a new version of an online toric intraocular lens (IOL) calculator in eyes implanted with a bitoric IOL.

Patients and methods: Retrospective observational comparative study in patients that underwent cataract surgery with implantation of the bitoric IOL AT TORBI 709M (Carl Zeiss Meditec AG, Jena, Germany). Visual and refractive outcomes were evaluated at 1 month after surgery. The selection of the toric IOL power was performed with the software Z CALC 2.0 (Carl Zeiss Meditec AG, Jena, Germany). The absolute refractive prediction error (ARPE) for the spherical equivalent (SE) and cylinder was calculated and compared with the values that would have been obtained using version 1.5 of the same software.

Results: A total of 393 eyes of 276 patients were evaluated. Mean postoperative sphere and cylinder were +0.03±0.54 and -0.19±0.30 D. A total of 95.67%, 98.22% and 95.17% of eyes had a postoperative sphere, cylinder and SE within ±1.00 D, respectively. Mean ARPE for SE was 0.34±0.27 D with the two versions of the Z CALC software. In contrast, a significantly higher ARPE value for the cylinder was found with Z CALC 1.5 compared to version 2.0 (0.35±0.32 vs. 0.28±0.30 D, $p<0.001$). The ARPE for cylinder was ≤0.25 D in 62.3% and 47.5% when using the version 2.0 and 1.5, respectively.

Conclusion: The use of an optimized software for toric IOL power calculation, considering the contribution of posterior corneal astigmatism, improved the astigmatic outcome with a bitoric IOL.

Keywords: IOL calculation software; toric intraocular lens; biometry; ZCALC; IOL formula

Introduction

Clinically significant errors in toric intraocular lens (IOL) power calculations can be induced, if the contribution of the posterior corneal surface to total corneal astigmatism is not considered.[1] Different methodologies have been developed and validated to take this contribution of posterior corneal astigmatism into account for the calculation of toric IOL power, providing different levels of optimization of clinical outcomes.[1-8] A coefficient of adjustment of 0.75 for with-the-rule (WTR) anterior corneal astigmatisms, and a coefficient of 1.41 for against-the-rule (ATR) astigmatisms was suggested by Goggin and coauthors[8] in toric IOL power calculations for cases requiring power values of 2 D of cylinder or less, according to calculations with unadjusted measurements. Eom et al[5] developed a new program for toric IOL power calculation, considering posterior corneal astigmatism, incision-induced posterior corneal astigmatism and effective lens position. In clinical practice, one widely used method for toric IOL power calculations is the Baylor toric IOL nomogram, due to its simplicity.[9] This approach is based on considering the effect of posterior corneal astigmatism to total corneal astigmatism by increasing the recommended corneal astigmatism ranges for implantation in eyes with ATR anterior corneal astigmatism and by decreasing them for eyes with WTR astigmatism.[9] Furthermore, the Abulafia-Koch regression formula was developed to calculate the estimated total corneal astigmatism based on standard keratometry measurements and to optimize toric IOL calculations.[10]

Online calculators of various IOL manufacturers are available as clinical tools for optimizing toric IOL power calculations. Carl Zeiss Meditec AG (Jena, Germany) developed an optimized online calculator for its toric IOLs, Z CALC, that considers the potential influence of posterior corneal astigmatism.[11] The prediction of postoperative refractive outcome has been demonstrated to be improved with this online calculator compared to conventional calculations, only considering anterior corneal keratometric values.[11] Recently, a new version of this online calculator (Z CALC 2.0, Carl Zeiss Meditec AG, Jena, Germany) has been released that incorporates a proprietary developed 4th generation IOL formula with compensation of the posterior corneal astigmatism and a completely new user interface design. It is designed for non-toric and toric Zeiss IOLs, as well as for IOL implantation after laser corneal refractive surgery. The aim of the current study was to evaluate the potential benefit of this new version of the Z CALC online calculator compared to its previous version in a large sample of eyes implanted with a bitoric IOL, which distributes the cylinder power symmetrically on the front and back surface of the IOL.[12]

Material and methods

Patients

This prospective observational comparative study included patients that underwent cataract surgery with implantation of the bitoric IOL AT TORBI 709M (Carl Zeiss Meditec AG, Jena, Germany), which is a foldable, one-piece, bitoric, monofocal aspheric lens made of a hydrophilic acrylic material with hydrophobic properties (overall length: 11.0 mm, optic diameter: 6.0 mm, angulation of haptics in relation to the IOL optic: 0º). Inclusion criteria for the study included the presence of visually significant cataract (corrected distance visual acuity (CDVA) > 0.3 logMAR), patients suitable for refractive lens exchange (cataract essentially), and presence of a corneal astigmatism of 0.50 D or more. The following conditions were considered as exclusion criteria: irregular corneal astigmatism, previous ocular surgery including laser refractive surgery, corneal degeneration including ectatic corneal disorders, any active ocular and/or systemic disease, abnormal iris, antecedents of glaucoma or retinal detachment, macular degeneration or retinopathy, and antecedents of severe ocular inflammation. All patients were adequately informed and signed a consent form, and the study adhered to the tenets of the Declaration of Helsinki.

Examination protocol

A full ophthalmologic examination was performed during the preoperative visit, including manifest refraction, logMAR uncorrected distance visual acuity (UDVA) and CDVA testing, slit lamp examination, corneal topography, optical biometry (IOLMaster v.3.01, Carl Zeiss Meditec AG, Jena, Germany), Goldmann applanation tonometry and fundoscopy. In all cases, the calculation of the toric IOL power and the expected residual refractive error was performed with the software Z CALC version 2.0 (Carl Zeiss Meditec AG, Jena, Germany). Once the IOL power was selected, the residual refraction was estimated using additional IOL power calculations with the Z CALC software version 1.5 and the Haigis formula. Target refraction was set to emmetropia in most of cases, although low levels of monovision were targeted in some cases. The Z CALC software considers the patient's refraction, keratometry, axial length (AL), anterior chamber depth (ACD), the theoretical surgically induced astigmatism, the anterior and posterior corneal astigmatisms, and the planned incision location to calculate the appropriate IOL power for implantation. Version 1.5 of the software estimates the total corneal astigmatism using the keratometric measurements and a statistical model of the posterior corneal correction based on the Gullstrand eye model. In contrast, version 2.0 estimates the total corneal astigmatism using the keratometric measurements and a statistical model of the posterior corneal correction based on a nomogram derived from clinical data showing improved results when compared with the Gullstrand model.

Postoperatively, patients were evaluated during a 1-month follow-up. At 1 day after surgery, only UDVA, tonometry and the integrity of the anterior segment were evaluated. At 1 month after surgery, the examination protocol was identical to the preoperative protocol, with the additional analysis of the IOL rotation at the slit lamp, assessing the position of the indentations locating the flat meridian of the optic.

Surgery

A bimanual micro-incision sutureless micro-biaxial phacoemulsification technique was performed by the same experienced surgeon in all cases using a corneal incision of 1.2 mm on temporal side. After manual creation of the capsulorrhexis, phacoemulsification and aspiration of the cortical material, the IOL was inserted into the capsular bag by means of the A6 injector and AT Smart cartridge (Carl Zeiss Meditec AG, Jena, Germany) by 1.6 mm with wound assist injection. Once inserted into the capsular bag, the IOL was rotated to align the IOL cylinder axis with the steepest corneal axis (axis of total astigmatism assessed with the Pentacam (Oculus, Wetzlar, Germany). The steepest meridian was marked with the image guided Callisto system (Carl Zeiss

Meditec AG, Jena, Germany). The same postoperative treatment was administered to all patients consisting of corticosteroid-antibiotic combination eye drops.

Statistical analysis

Data tabulation and statistical operations were performed with Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash) and SAS 9.1 (SAS Institute Inc, Cary, NC). Normality of all data samples was evaluated with the Kolmogorov-Smirnov test. The Student t test for paired data was used for refractive comparisons between results with the two versions of Z CALC when parametric analysis was possible. The Wilcoxon Rank Sum test was used to assess the significance of differences between software versions when parametric analysis was not possible. The level for statistical significance was set to $p<0.05$.

Results

A total of 393 eyes of 276 patients with a mean age of 76.1 years (Standard deviation, SD: 8.6; median: 77.0; range: 46 to 95 years) were included. The ocular geometric and IOL data are shown in table 1.

Refractive outcomes

Postoperative refractive data are shown in table 2. One month after surgery, 95.67% (376), 98.22% (386) and 95.17% (374) of eyes had a postoperative sphere, cylinder and SE within ±1.00 D, respectively (Figure 1). Furthermore, postoperative sphere, cylinder and SE was within ±0.50 D in 78.63% (309), 92.11% (362) and 75.83% (298), respectively (Figure 3).

Refractive prediction error

Mean predicted postoperative SE with the Z CALC 2.0 software was -0.10 D (SD: 0.42, median: -0.09, range: -1.57 to +1.12 D). Mean absolute refractive prediction error (ARPE) (difference between target and postoperative real SE) was 0.34 D (SD: 0.27, median: 0.28, range: 0.00 to 1.57 D), with 98.7% achieving a value of ARPE of 1 D or below (Figure 2). Assuming the same refractive target with both versions of Z CALC, a significantly higher ARPE cylinder value was found when using version 1.5 of Z CALC, compared to version 2.0 ($p<0.001$) (Figure 3). The ARPE cylinder value was 0.25 D or below in 62.3% of cases when using Z CALC version 2.0, whereas this percentage was 47.5% when using version 1.5 (Figure 2). No significant differences were found between software versions regarding the ARPE value for SE ($p=0.428$) (Figure 3).

Discussion

The consideration of the effect of posterior corneal astigmatism on total corneal astigmatism when performing toric IOL power calculations has been shown to be relevant for optimizing clinical outcomes.[1,4,9,13] In the current study, a comparative analysis of the outcomes obtained after cataract surgery with implantation of a bitoric IOL was performed, using two versions of a software for IOL power calculation based on different approaches in terms of considering the contribution of the posterior corneal surface to corneal astigmatism. In all patients, the same bitoric IOL, AT TORBI 709M, was implanted. The outcomes with this specific IOL have been previously reported by other authors, confirming the efficacy and safety of the refractive correction achieved.[11,12,15-18] In the current sample, 98.22% and 92.11% of eyes had a postoperative cylinder within 1.00 and 0.50 D, respectively. This outcome was better than that reported for the same model of toric IOL by previous authors, using standard methods of IOL power calculation without considering the contribution of the posterior corneal surface.[12,14,16-18] Kretz et al[14] found in a sample of 41 eyes implanted with the AT TORBI 709M IOL that 86% and 95% of eyes had a postoperative absolute value of refractive cylinder of 0.50 D or less and 1.00 D or less, respectively. Kern and colleagues[11] demonstrated that considering only anterior corneal keratometric values for the power calculations of the same bitoric IOL may lead to postoperative undercorrection of astigmatism.

For ARPE of the spherical equivalent, a mean value of 0.34 ± 0.27 D was found with the two versions of the Z CALC software. In contrast, mean ARPE for cylinder was 0.35 ± 0.32 and 0.28 ± 0.30 D with the versions 1.5 and 2.0 of Z CALC, respectively. This difference reached statistical significance, indicating that there was a significant benefit on using the newer the version in terms of predictability of the astigmatic correction, although both options provided acceptable clinical outcomes. Therefore, optimized algorithms for considering the effect of posterior corneal astigmatism, such as Z CALC 2.0, should be used, when calculating the toric IOL power for eyes with pre-existing corneal astigmatism. Kern et al[11] performed a study on the refractive prediction error, comparing a standard calculator using IOLMaster 500 (Carl Zeiss Meditec AG, Jena, Germany) anterior corneal keratometry, followed by recalculation using the Barrett calculator for eyes implanted with the same bitoric IOL as in the current study. Specifically, they found that the Barrett calculator predicted a lower residual cylinder than the standard calculator. A prediction of a significantly higher residual cylinder was obtained with the standard calculator for patients with WTR astigmatism. For ATR astigmatism, these authors found that differences between standard and Barrett calculators in terms of cylinder prediction error did not reach statistical significance.[14] The Barrett calculator suggested a lower toric cylinder (3.22 vs. 3.00 D) compared to the standard method.[14] Canovas and colleagues[3] demonstrated that the use of a new self-developed posterior corneal astigmatism algorithm reduced the error in the prediction of residual refractive astigmatism in eyes implanted with toric IOLs. In another comparative study, the Barrett toric calculator and the Abulafia-Koch formula, both considering the potential contribution of the posterior corneal surface, provided the lowest astigmatic prediction errors compared to other options of IOL power calculation.[13]

Several factors may have accounted for the improvement in astigmatic refractive prediction of version 2.0 compared to version 1.5 of Z CALC. The ARPE cylinder value was 0.25 D or below in 62.3% and 47.5% of cases with Z CALC 2.0 and 1.5, respectively, with no significant differences between software versions in ARPE for SE. One crucial factor for explaining this finding is that version 2.0 considers real clinical data and is not only based on theoretical calculations using a paraxial eye model composed of coaxial elements. This confirms that not only considering the effect of the magnitude of posterior corneal astigmatism on total corneal astigmatism is relevant, but also the contribution of the axis of astigmatism and even of corneal thickness, especially in pathological or thin corneas.[2] Koch et al[19] demonstrated, that selecting toric IOLs based on anterior corneal measurements could lead to overcorrection in eyes that with WTR astigmatism and undercorrection in eyes with ATR astigmatism. Indeed, some current formulas and algorithms for toric IOL power calculations are based on considering these specific trends for eyes with WTR and ATR astigmatisms.[1,6,9] However, there are specific cases that may not follow these trends, as well as cases with oblique astigmatism, with more variability in terms of contribution of posterior to total corneal astigmatism.[2] For this reason, the included analysis of real clinical data may refine these potential inaccuracies. Furthermore, this empirical algorithm may also account for the potential effect of corneal incision during cataract surgery and help to avoid misalignment of toric IOLs. It has been demonstrated that misalignment of a toric IOL can generate an ineffective correction of astigmatism due to the reduced corrective effect.[20-22] Bascaran et al[12] found that IOL misalignment was 4.42 ± 4.31º using the same model of bitoric IOL implanted in the current sample, with 86% of the lenses being off less than 10 degrees of the targeted axis. Mencucci and coauthors[16] found a mean misalignment for the same model of toric IOL of 2.66 ± 1.53º and 3.00 ± 1.69º at 3 and 6 months after surgery, respectively, with 95% and 90% of eyes within ±5 degrees.

Conclusion

The use of the Z CALC version 2.0 allows a more predictable selection of cylindrical IOL power of the bitoric IOL AT TORBI 709M than its predecessor version 1.5, most probably due to the optimized algorithm. The calculation is based on empirical data for considering the contribution of posterior corneal astigmatism to total corneal astigmatism and consequently to the final cylindrical power of the toric IOL. Future studies should be considered with other models of toric IOLs as well as in eyes with pathological corneas, such as keratoconus, in order to confirm the usefulness of this new algorithm for toric IOL power calculation in other clinical situations.

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Disclosure

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Table 1 Preoperative ocular and IOL data

Parameter	**Mean ± SD**	**Median**	**Range**
Axial length, mm	23.64 ± 1.28	23.49	20.66 to 31.60
Anterior chamber depth, mm	2.99 ± 0.37	2.98	2.07 to 4.23
Anterior corneal astigmatism, D	1.24 ± 0.77	1.03	0.50 to 6.38
IOL spherical power	19.78 ± 3.56	20.5	1.50 to 30.00
IOL cylinder power	1.60 ± 0.83	1.50	1.00 to 5.50

Abbreviations: SD, standard deviation; D, diopter; mm, millimeter

Table 2 Postoperative manifest refraction 1 month after surgery

Parameter	Mean ± SD	Median	Range
Sphere, D	**0.03 ± 0.54**	**0**	**-2.50 to 2.00**
Cylinder, D	**-0.19 ± 0.3**	**0**	**0.00 to -1.75**
Spherical equivalent, D	**-0.06 ± 0.53**	**0**	**-2.50 to 1.50**

Abbreviations: SD, standard deviation; D, diopter

Figure 1 Distribution of postoperative manifest sphere, cylinder and spherical equivalent (SE)

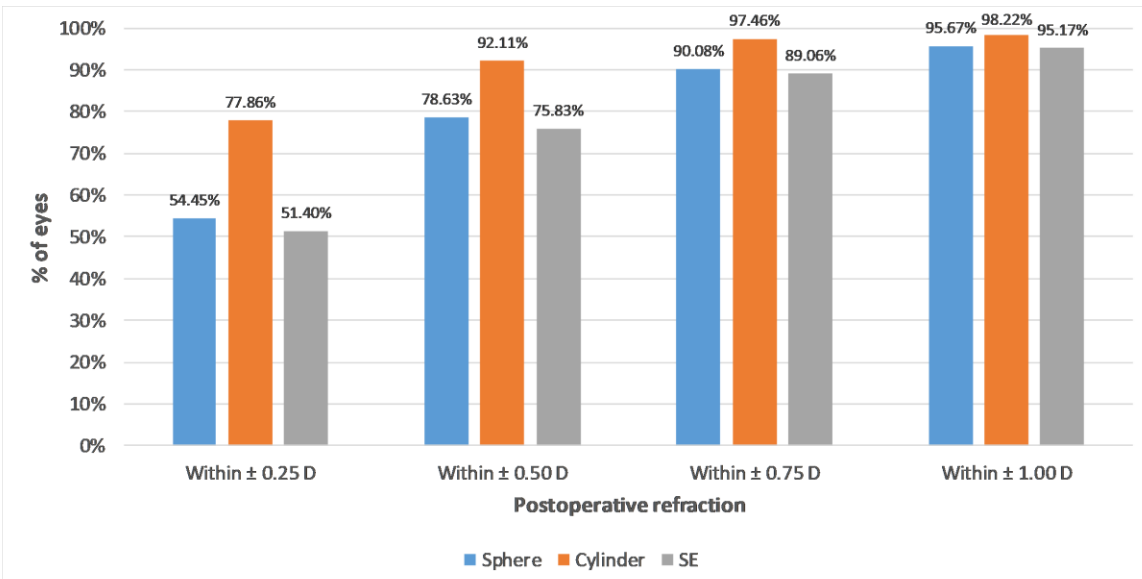

Figure 2 Distribution of the absolute refractive prediction error (ARPE) for spherical equivalent (SE) and cylinder using the versions 1.5 and 2.0 of the Z CALC software

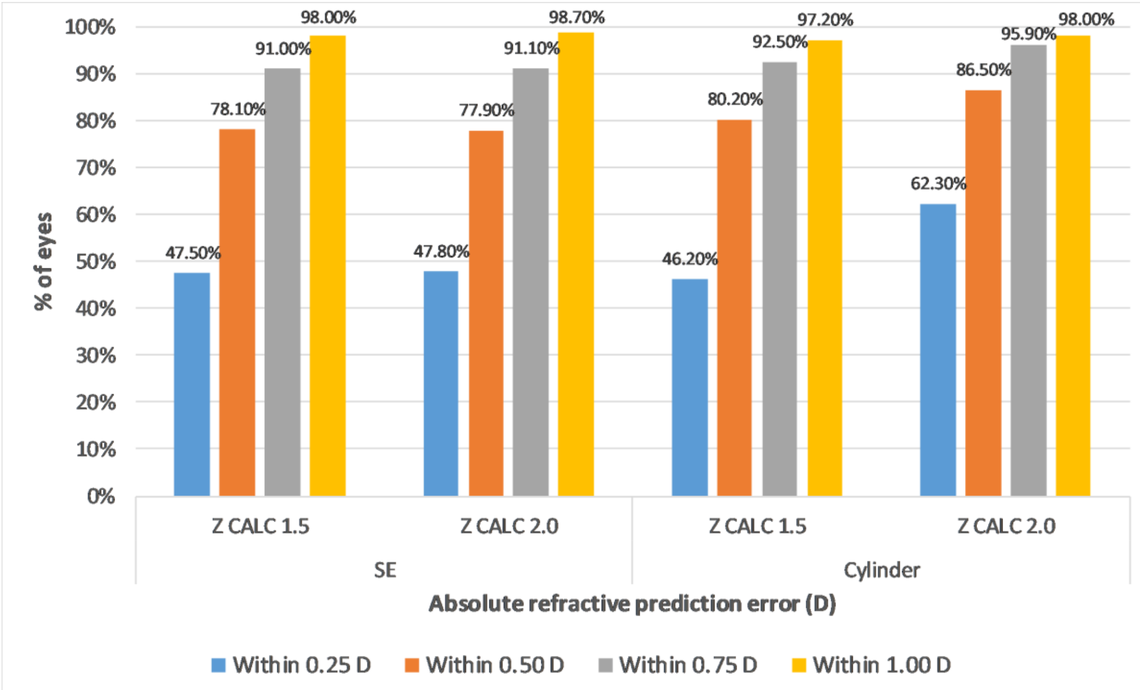

Figure 3 Mean values of the absolute refractive prediction error (ARPE) for spherical equivalent (SE) and cylinder using the versions 1.5 and 2.0 of the Z CALC software